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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY, *Plaintiff,* v. ACTAVIS ELIZABETH LLC, GLENMARK PHARMACEUTICALS INC., USA, SUN PHARMACEUTICAL INDUSTRIES LIMITED, SANDOZ INC., MYLAN PHARMACEUTICALS INC., APOTEX INC., AUROBINDO PHARMA LTD., TEVA PHARMACEUTICALS USA, INC., SYNTHON LABORATORIES, INC., ZYDUS PHARMACEUTICALS, USA, INC., *Defendants.*	)	Civil Action No. 07-3770 (DMC) (MF)

REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OF INVALIDITY OF U.S. PATENT NO. 5,658,590

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INTRODUCTION

U.S. Patent No. 5,658,590 ("the '590 patent") is obvious and defendants' arguments are simple: it is undisputed that, prior to 1995, it was known that (1) desipramine was effective in treating attention-deficit/hyperactivity disorder ("ADHD"), (2) desipramine's effectiveness in treating ADHD was due to its selective inhibition of the reuptake of norepinephrine, and (3) atomoxetine and desipramine have nearly identical action in selectively blocking the reuptake of norepinephrine—they are both "SNRIs". Thus, a person of ordinary skill would have been motivated to substitute atomoxetine for desipramine to treat ADHD. Further, because a finite number of SNRIs were available prior to 1995, it would have been obvious for one of ordinary skill to try atomoxetine for ADHD. Nothing more is needed to establish obviousness under *KSR*.

Instead of refuting these compelling obviousness arguments, Lilly raises irrelevant arguments and attempts to confuse the Court. Lilly's brief is rampant with mischaracterizations of the prior art, misapplications of the law, and immaterial misdirections. For instance, in attempting to create issues of material fact, Lilly purposefully introduces medical terminology and issues that are not material to the obviousness analysis, specifically: the etiology and pathophysiology of ADHD (*i.e.*, the cause or functional changes in the brain associated with the disorder), and the downstream mechanism of action of drugs used for ADHD (*i.e.*, all possible biological consequences of a drug in the brain beyond the initial physical interaction). Whether these were known was unnecessary in finding a new use for an old drug, as Lilly did here. In fact, the etiology and pathophysiology of ADHD and the downstream mechanism of action of atomoxetine and other drugs used for ADHD remain unknown to this day.

The prior art renders the '590 patent obvious, but if this Court finds otherwise, then based on Lilly's own admissions that a person of ordinary skill would not have reasonably expected that atomoxetine would work for ADHD, the patent cannot be enabled. Its woefully deficient

disclosure fails to establish any practical utility adequate to convince one of ordinary skill that atomoxetine would have been useful for ADHD. There was also nothing in the prior art (according to Lilly) to establish utility. The only support that Lilly can muster for purported utility is *post-filing* data obtained from the proof-of-concept study at Massachusetts General Hospital. However, as a matter of law, such *post-filing* data cannot retroactively cure Lilly's grossly inadequate specification. Lilly tries to avoid the prior art that renders the patent obvious on the one hand and, on the other, tries to argue sufficient disclosure of utility in a patent that has no such disclosure. Lilly cannot have it both ways. Either way, the '590 patent is invalid.

ARGUMENT

I. Lilly's Arguments Are Not Material to Obviousness

In a spurious attempt to create issues of material fact when none exists, Lilly injects irrelevant issues including what causes ADHD and how desipramine works downstream, but these issues are not material to determining obviousness (nor are they necessary for any drug development). *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) ("Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment.").

A. What Causes ADHD Is Immaterial to the Obviousness Analysis

Lilly argues that, because the etiology of ADHD was unknown and there was no consensus as to what areas of the brain or what neurotransmitters were involved, there was no clear starting point for targeting specific mechanisms of action to treat ADHD. This conclusion is flawed and the supporting prior art that Lilly cites (*i.e.*, the 1989 Mefford and Potter article and the 1991 McCracken article) is immaterial to the determination of obviousness.

That the etiology and pathophysiology of almost all psychiatric and behavioral disorders, including ADHD, were unknown would not have discouraged one skilled in the art from treating

these disorders. It is ridiculous to assert otherwise. Rather, it was customary practice to use a drug's known mechanism of action as a starting point for developing new treatments. This real-world approach is precisely what Lilly's Dr. Heiligenstein followed. Prior to 1995, it was well known that tricyclic antidepressants ("TCAs"), particularly desipramine, were effective in treating ADHD and that desipramine's effectiveness was attributed to its selective inhibition of norepinephrine reuptake.[1] One skilled in the art would have readily concluded that desipramine was a perfect starting point to identify other SNRIs for treating ADHD, and that skilled artisan would have had a reasonable expectation of success in treating ADHD with an SNRI.

B. The Mechanism of Action of ADHD Drugs Including Desipramine Was Well Known; Downstream Effects of these Drugs Are Immaterial

Lilly again attempts to confuse the issue by arguing that, because different classes of drugs with various mechanisms of action were explored to treat ADHD, there is no way to reconcile "how each of the drugs might work." Lilly relies on the 1992 Shenker article to argue that there was no unifying "pharmacological model" to reconcile the various ADHD treatments. These facts are irrelevant. The only facts that are material to the obviousness analysis are that desipramine and atomoxetine share the same mechanism of action and desipramine was effective in treating ADHD. Thus, it would have been obvious to use atomoxetine for ADHD, and in doing so, the skilled artisan would have had a reasonable expectation of success. It is that simple.

To support its contention that a single neurotransmitter hypothesis was untenable and that the prior art taught that multiple neurotransmitters were necessary to treat ADHD effectively, Lilly takes out of context one line from the 1987 Zametkin and Rapoport article and cites to

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[1] *See, e.g.,* Robinson Cert. (D.E. 291), Ex. Q at 147, 170, 180; Ex. T at 73, 79; Ex. R at 777, 783. *See also* Second Robinson Cert., Ex. YY at 145. "Second Robinson Cert., Ex. __" refers to the Second Certification of Brian J. Robinson in Support of Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 5,658,590, filed concurrently herewith.

nothing else. But that article states that "[a] role for norepinephrine metabolism in the . . . treatment of this disorder is highly likely" – entirely consistent with the prior art as a whole, which taught that desipramine, an SNRI, was effective in treating ADHD.[2]

Lilly further mischaracterizes the prior art and deposition testimony to support its contention that the prior art lacked any suggestion to use an SNRI because desipramine has a complex mechanism of action. While desipramine's downstream mechanism may not have been fully understood, prior to 1995, those skilled in the art understood that desipramine's mechanism of action—the selective inhibition of norepinephrine reuptake—was responsible for its effectiveness in treating ADHD.[3]

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II. The Undisputed Material Facts Demonstrate that the '590 Patent Would Have Been Obvious under the Supreme Court's Decision in *KSR*

A. The Prior Art Suggested the Use of Atomoxetine for ADHD

Lilly devotes page after page of its brief discussing the unknown etiology of ADHD and outlier pieces of prior art that it alleges teach away from using an SNRI to treat ADHD. Yet, the prior art as a whole taught that desipramine is an SNRI that is effective in treating ADHD and a person of ordinary skill in the art would have been motivated to substitute atomoxetine for desipramine in the treatment of ADHD.[5]

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[2] Second Robinson Cert., Ex. ZZ at 684. *See also, e.g., id.*, Ex. YY; Ex. AAA; Ex. DDD; D.E. 291, Ex. Q; Ex R; Ex. S; Ex. T; Ex. U; Ex. V; Ex. Z.

[3] *See, e.g., id.*

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[5] Contrary to Lilly's assertion, the U.S. Patent and Trademark Office ("USPTO") never considered this argument. Rather, the USPTO was misled by Lilly's prosecution arguments that TCAs (including desipramine) and atomoxetine have nothing in common: "[a]tomoxetine is a (continued...)

Lilly's nonobviousness argument is that the prior art contained different approaches for ADHD research, each of which allegedly taught away from using an SNRI to treat ADHD. This argument directly conflicts with the Supreme Court's decision in *KSR*. In *KSR*, the Court found that it would have been obvious for one of ordinary skill to pursue a number of different options:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

550 U.S. 398, 421 (2007). Here, the prior art as a whole would have motivated a person of ordinary skill to pursue atomoxetine as one of the "known options within his or her technical grasp." Specifically, because there were a finite number of SNRIs available prior to 1995 and they had been proven effective for ADHD, it would have been nothing more than just another predictable solution within the knowledge of the skilled artisan to treat ADHD with atomoxetine.

Moreover, a person of ordinary skill would have had a reasonable expectation of success. "[T]he expectation of success need only be reasonable, not absolute" or "a guarantee." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007) ("[O]bviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success."). Given the widespread success in treating ADHD with desipramine prior to 1995, and given that desipramine and atomoxetine are both SNRIs, it would have been reasonable for one of ordinary skill to expect that atomoxetine would work to treat ADHD.

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highly selective and specific norepinephrine inhibitor, which is not suggested by the numerous activities of the prior art tricyclics." Also, the USPTO was not given prior art showing that desipramine is a highly selective norepinephrine reuptake inhibitor, just like atomoxetine. Thus, it was never conveyed to the USTPO that desipramine is an SNRI that has nearly identical action as atomoxetine.

The facts in this case bear a striking similarity to those in *Imperial Chemical Industries, PLC v. Danbury Pharmacal, Inc.*, 777 F. Supp. 330 (D. Del. 1991). There, the court held that a patent claim directed to a method of treating hypertension with a compound that belonged to a class of compounds already known to treat hypertension was invalid as obvious. *See id.* at 373. As here, prior to the patent application's filing date, the inventors did not do any testing on the compound, atenolol, for its use in treating hypertension. Noting that "[t]he prior art teaches the way in which this class of compounds functions and the uses for this class of compounds," the court held that the patent was invalid. *Id.* at 347. Applying that reasoning here, the '590 patent is likewise invalid as obvious.

Lilly's argument that defendants' obviousness case is based on hindsight is without merit. Defendants properly consider what a person of ordinary skill knew and would have done in 1995. The fact that no one had yet created the claimed "invention" cannot defeat obviousness because that is true in every challenge to a patent's validity based on obviousness. If that were the standard, no patented invention can ever be obvious.

B. The Sudden Deaths Allegedly Associated with Desipramine Treatment Would Lead a Person of Ordinary Skill *Toward* Treating ADHD with Atomoxetine

Lilly cites *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007), and argues that reports of sudden deaths of children taking desipramine led away from pursuing it as a lead compound. First, Lilly's reliance on *Takeda* is misplaced. The present case does not involve a compound patent and does not involve choosing a lead compound out of hundreds of millions of possible compounds; rather it involves a method of using an old drug whose mechanism of action was well known. Second, contrary to Lilly's assertions, doctors continued to use desipramine after 1990. In fact, Dr. Biederman, the "leading researcher in desipramine" according to Lilly, published several articles after 1990 concerning

his research on desipramine, including its use to treat ADHD in children.[6] Third, the sudden deaths allegedly associated with desipramine would have motivated a person of ordinary skill to substitute atomoxetine for desipramine because, as Lilly concedes, atomoxetine lacks the receptor activity (which is entirely different from reuptake inhibition activity) that desipramine possesses and that cause side effects.[7] Thus, far from establishing nonobviousness, Lilly's argument about sudden deaths supports a finding that the claims of the '590 patent would have been obvious.

C. Lilly Has Provided No Persuasive, Reliable Evidence of Secondary Considerations To Overcome Obviousness

Lilly's evidence on secondary considerations of non-obviousness is insufficient to overcome the clear and convincing evidence that the use of atomoxetine to treat ADHD was obvious based on the prior art. Lilly's argument that atomoxetine met a long-felt need is belied by the fact that those of ordinary skill **REDACTED** used non-stimulant drugs to treat ADHD.[8]

Further, Lilly has failed to meet its burden to establish that the alleged commercial success of Strattera® is due to a feature claimed in the '590 patent. *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997) (a party cannot "demonstrate commercial success, for purposes of countering the challenge of obviousness, unless it can show that the commercial success of the product results from the claimed invention."). If anything, the alleged commercial success of Strattera® is attributable to the compound atomoxetine claimed in the '081 patent, not the method claimed in the '590 patent. *See Merck & Co., Inc., v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005) ("Because market entry by others was precluded on those bases, the inference of non-obviousness . . . from evidence of

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6 *See, e.g.*, D.E. 291, Ex. R; Ex. Y.

7 *See, e.g.*, D.E. 291, Ex. R at 777-778; Ex. V at 906; Ex. Z at 64.

commercial success, is weak."). Thus, Lilly cannot establish a nexus between the sales of Strattera® and the claimed method. There is likewise no nexus between the alleged praise for Strattera® and the claimed method of the '590 patent.[9]

Finally, Lilly's argument that ten defendants sought FDA approval to market generic atomoxetine is evidence of nonobviousness is flat out wrong. Contrary to Lilly's assertions, defendants *did not copy Lilly's product* – defendants merely mirrored certain portions of Strattera®'s label as required by the FDA.[10] The Hatch-Waxman Act provides for such "copying"; it was designed to promote the development of affordable generic drugs and encourage challenges to weak patents, such as the '590 patent. Multiple defendants filed ANDAs here because they all viewed the '590 patent as extraordinarily weak and thus highly vulnerable to invalidation, especially in light of compelling prior art and a flimsy specification.

Thus, none of the evidence cited by Lilly overcomes the finding of obviousness.

III. If Not Obvious, Then the '590 Patent Is Not Enabled

In this case, the '590 patent is either obvious or not enabled. Either defendants are correct that the patent would have been obvious or, if there is nothing in the prior art to suggest the use of atomoxetine for ADHD, then there is nothing in the prior art to buttress Lilly's bare-bones patent disclosure, and consequently the '590 patent is not enabled for lack of utility.

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8 *See* D.E. 300 at 17. *See also* Second Robinson Cert., Ex. FFF at 254.

9 *See* D.E. 300 at 17-18. Nothing highlights Lilly's desperation to show nonobviousness more than its reliance on the Spencer "affidavit," a document produced by Lilly as discovery closed and after Dr. Spencer's deposition. The "affidavit" fails to meet the requirements of 35 U.S.C. § 1746, is unauthenticated and is inadmissible hearsay. Moreover, Magistrate Judge Falk directed Lilly to make Dr. Spencer available for deposition if it wished to rely on the "affidavit." Not surprisingly, Lilly never produced Dr. Spencer, and having successfully shielded Dr. Spencer from cross examination, Lilly is in no position to proffer his "affidavit."

10 *See* D.E. 300 at 16.

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Lilly's nonobviousness arguments support defendants' position that the '590 patent is not enabled. Lilly argues that as of the filing date: (i) "there would be no reasonable assurance that atomoxetine would work to treat ADHD," (ii) that one of ordinary skill would not "reasonably expect that it would work," (iii) that the prior art taught "that affecting NE alone was not enough to treat ADHD," and (iv) that "the field of ADHD treatments was unpredictable and what little direction there was pointed away from using atomoxetine to treat ADHD."

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Taking these admissions as true, and given the defective disclosure of the '590 patent, a person of ordinary skill would not have accepted "without question" that atomoxetine would work for ADHD without supporting data as of the filing date of the '590 patent. Nothing more is needed to find the patent invalid for lack of enablement under § 112 according to *Rasmusson*. *Rasmusson v. Smith-Kline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005).

At best, Lilly's patent specification provided an expectation of utility because testing with atomoxetine as a potential treatment for ADHD had never been done. This yet-to-be executed research, however, was nothing more than a plan to experiment and it is insufficient to satisfy the utility requirement of enablement:

> If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to "inventions" consisting of little more than respectable guesses as to the likelihood of their success. When one of the

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> guesses later proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked.

Id. at 1325, *see also Brenner v. Manson*, 383 U.S. 519, 536 (1966) ("a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."); *Hitzeman v. Rutter*, 243 F.3d 1345, 1357 (Fed. Cir. 2001) (holding that policy behind the patent laws is to "promote disclosure of inventions, not of research plans"); *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1374-75 (Fed. Cir. 1999) (no enablement when "the teachings set forth in the specifications provide no more than a 'plan' or 'invitation' for those of skill in the art to experiment."); *In re: '318 Patent Infringement Litigation*, Civ. No. 05-356, 2008 U.S. Dist. LEXIS 65951, at *66-67 (D. Del. Aug. 27, 2008) (no enablement when the patent-in-suit "only surmises how the claimed method could be used, rather than teach one of skill in the art how to use the claimed method."). Lilly's strategy of filing more than fifteen patent applications in the United States that disclose mere guesses at methods of using atomoxetine—like throwing darts—is not sufficient to meet the utility requirement of enablement.

B. Lilly Cannot Rely on Post-Filing Data To Establish Enablement

To save its patent, Lilly suggests that post-filing data from the proof-of-concept study are sufficient to retroactively establish utility.[12] This argument misses the mark and fails as a matter of law. A patent application *as filed* must contain a disclosure that establishes the asserted utility; deficiencies in disclosure cannot be corrected at a later date. *See In re Fisher*, 421 F.3d 1365, 1371 (2005) ("It thus is clear that an application must show that an invention is useful to

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[12] Lilly could have saved its patent (but not its original filing date) by filing a continuation-in-part application ("CIP") under 37 CFR 1.53(b) to submit the data from the proof-of-concept study. That Lilly did not is inexplicable, but its failure cannot be corrected by later studies never added into the application. In *Rasmussen*, the applicants had in fact filed a CIP with data supporting utility, but the court determined that they were not entitled to the priority date of the earlier application that lacked that data. 413 F.3d at 1327.

the public as disclosed in its current form, not that it may prove useful at some future date after further research."); *Rasmusson*, 413 F.3d at 1324 (rejecting patentee's attempt to establish utility based on data that post-dated the application); *In re Gardner*, 427 F.2d 786, 789 (CCPA 1970) ("the law requires that the disclosure in the application shall inform them how to use, not how to find out how to use for themselves" by adding "a great amount of work").

Post-filing and extrinsic evidence can only show whether the patent was enabled when it was filed. In the cases cited by Lilly, the court allowed such evidence because it substantiated what was known or believed at the time of filing, not after. For example, in *In re Brana*, the court allowed reliance on a post-filing declaration to bolster the specification's "explicit reference" to prior art disclosing *in vivo* testing:

> The [] declaration, though dated after applicants' filing date, can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification. It does not render an insufficient disclosure enabling but instead goes to prove that the disclosure was in fact enabling when filed (i.e., demonstrated utility).

51 F.3d 1560, 1567, n.9 (Fed. Cir. 1995) (citations omitted).[13] Thus, Lilly's argument that post-filing data establishes utility is wrong as a matter of law and must be rejected.

It is undisputed that the '590 patent specification provides absolutely no data regarding the use of atomoxetine to treat ADHD, and by Lilly's own admissions, one of ordinary skill would not accept without question that atomoxetine could be used to treat ADHD. Under *Rasmusson*, the '590 patent is not enabled for lack of utility and thus invalid.

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[13] In *Gould v. Quigg*, the court concluded that an expert properly relied on a later-dated publication *in forming his opinion* as to whether or not the disclosure was enabling *at the time of filing*. 822 F.2d 1074, 1078 (Fed. Cir. 1987) ("As to the technical article, it is true that a later dated publication cannot supplement an insufficient disclosure in a prior dated application to render it enabling. In this case, the later dated publication was not offered as evidence for this purpose. Rather, it was offered as evidence of the level of ordinary skill in the art at the time of the application and as evidence that the disclosed device would have been operative.")

CONCLUSION

Under *KSR*, the undisputed material facts demonstrate that the '590 patent would have been obvious to one of ordinary skill prior to 1995. Should the Court find that using atomoxetine to treat ADHD would have been non-obvious, then the '590 patent is not enabled as those of ordinary skill in the art would not have accepted without question that atomoxetine could be used to treat ADHD. Either way, the '590 patent is invalid for the reasons discussed above.

Dated: July 27, 2009

Respectfully Submitted,

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